ATTORNEY DOCKET NO.: 0492611-0326 (8151)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Robert S. Langer and David A. Putnam

Serial No.:

09/553,552 04/20/2000

Filed: For:

ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS



VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS 37 CFR 1.9(f) and 1.27(d) NON-PROFIT ORGANIZATION

hereby declare that I am an official empowered to act on behalf of the non-profit organization

NAME OF ORGANIZATION:

Massachusetts Institute of Technology

ADDRESS OF ORGANIZATION: 77 Massachusetts Avenue

Cambridge, Massachusetts 02142

TYPE OF ORGANIZATION:

| (| X | .) | University | or other | organization | of higher | education |
|---|---|----|------------|----------|--------------|-----------|-----------|
| | | | | | | | |

| () | Non-profit scientific or educational organization under a statute of a state of the |
|-----|---|
| | United States of America |
| | NAME OF STATE: |
| | CITATION OF STATUTE: |
| | |

- () Would qualify as tax exempt under the Internal Revenue Service Code (26 USC 501(a) and 501(c) (3) if the organization were located in the United States of America
- () Tax exempt under the Internal Revenue Service Code (26 USC 501(a) and 501(c) **(3)**.
- () Would qualify as a non-profit scientific or educational organization under a statute of a state of the United States of America NAME OF STATE: CITATION OF STATUTE:

I hereby declare that the above-identified non-profit organization qualifies as a non-profit organization as defined in 37 CFR 1.9(e), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code.

I hereby declare that rights under contract or law have been conveyed to and remain with the above-identified non-profit organization with regard to the invention titled:

| TITLE: | Endosomolytic Agents and Cell Delivery Systems | | |
|---------------------------------------|---|--|--|
| by: | | | |
| INVENTOR | S: Robert S. Langer and David A. Putnam | | |
| described in: | | | |
| () | the specification filed herewith | | |
| (X) | U.S. Patent Application Serial Number 09/553,552 filed 04/20/2000 | | |
| () | U.S. Patent Numberissued | | |
| concern, or of invention are | of the above-identified non-profit organization are not exclusive, each individual, organization having rights to the invention is listed below* and no rights to the held by any person, other than the inventor(s), who could not qualify as a small tern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e). | | |
| | eparate verified statements are required from each named person, concern, or having rights to the invention, averring to their status as small entities. (37 CFR | | |
| FULL NAMI ADDRESS: () INDIVIDI | E: JAL () SMALL BUSINESS CONCERN () NON-PROFIT ORGANIZATION | | |
| FULL NAMI ADDRESS: () INDIVIDI | E: UAL () SMALL BUSINESS CONCERN () NON-PROFIT ORGANIZATION | | |
| FULL NAMI ADDRESS: () INDIVIDI | E: UAL () SMALL BUSINESS CONCERN () NON-PROFIT ORGANIZATION | | |
| | | | |

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the

earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such

willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

JOHN H. TURNER, JR. ASSOCIATE DIRECTOR

TITLE IN ORGANIZATION:

TECHNOLOGY LICENSING OFFICE

ADDRESS OF PERSON SIGNING: Massachusetts Institute of Technology

77 Massachusetts Avenue, Room NE25-230

Cambridge, Massachusetts 02142

Exchange.3116819.1

Attorney Docket No. 0492611-0326 (8151)

| COMBINED D | ECLARATION AND POWER OF ATTORNEY |
|---|--|
| As a below named inver | ntor, I hereby declare that: |
| This declaration is origin | ntor, I hereby decrare that: |
| My residence, post offic | e address and citizenship are as stated below next to my name. |
| original, first and joint inventor | al, first and sole inventor (if only one name is listed below) or an (if plural names are listed below) of the subject matter which is is sought on the invention entitled: |
| ENDOSOMOLY | TIC AGENTS AND CELL DELIVERY SYSTEMS |
| the specification of which (I aut choices, and fill in the blanks, it | horize Choate, Hall & Stewart to check one of the following, three fapplicable): |
| is attached hereto. | |
| | 20/2000 as Application Serial No. 09/553,552 and amended on blicable). |
| | international application No, on as amended under PCT Article 19 on (if |
| | e reviewed and understood the contents of the above-identified ms, as amended by any amendment referred to above. |
| • | to disclose information which is material to the examination of with Title 37, Code of Federal Regulations, §1.56. |
| foreign application(s) for patent | riority benefits under Title 35, United States Code, §119 of any or inventor's certificate listed below and have also identified or patent or inventor's certificate having a filing date before that of y is claimed: |
| Prior Foreign Application(s): | Priority Claimed |
| (Number) (Country) | (Day/Month/Year/Filed) Yes No |

(Day/Month/Year/Filed)

Yes No

(Number)

(Country)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

| 60/130,362 | <u>4/21/99</u> | Pending |
|--------------------------|---------------------------|---------------------------------------|
| (Application Serial No.) | (filing date) | (status-patented, pending, abandoned) |
| (Application Serial No.) | (filing date) | (status-patented, pending, abandoned) |
| PCT Applications design | nating the United States: | |
| (PCT Appl. No.) | (U.S.S.N.) | (status-patented, pending, abandoned) |

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Sam Pasternack, Reg. No. 29,576; Brenda Herschbach Jarrell, Reg. No. 39,223; Kevin M. Tormey, Reg. No. 41,351; Elizabeth E. Nugent, Reg. No. 43,839; Karoline K.M. Shair, Reg. No. 44,332; Valarie B. Rosen, Reg. No. 45,689; Stanley C. Mah, Reg. No. 46,189.

Address all telephone calls to Karoline K.M. Shair at telephone no. (617) 248-5000.

Address all correspondence to <u>Karoline K.M. Shair</u>, Choate, Hall & Stewart, Exchange Place, 53 State Street, Boston, Massachusetts 02109-2891.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

| Full name of first inventor: Robert S. Langer | |
|--|---------------------------------------|
| Inventor's signature: | /Date: 9/5/00 |
| Residence: 77 Lombard Street, Newton, MA 021 | 58 |
| Citizenship: <u>USA</u> | · · · · · · · · · · · · · · · · · · · |
| Post Office Address: Same | |
| Full name of second inventor: <u>David A. Putnam</u> | |
| Inventor's signature: | _Date: |
| Residence: 143 Otis Street, Cambridge, MA 0214 | 41 |
| Citizenship: USA | |
| Post Office Address: Same | |

Exchange.3116827.1

Attorney Docket No. 0492611-0326 (8151)

ASSIGNMENT

WHEREAS, We, Robert S. Langer of Newton, Massachusetts and David A. Putnam of Cambridge, having invented certain new and useful improvements in ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS for which we will make application for United States Letters Patent; and

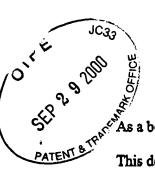
WHEREAS, MASSACHUSETTS INSTITUTE OF TECHNOLOGY a non-profit educational institute having offices at 77 Massachusetts Avenue, Cambridge, Massachusetts, and its successors and assigns (collectively hereinafter called "the Assignee"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledge, I do hereby sell assign and transfer unto said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive right, title and interest in and to said invention and in and to said application and all patents which may granted therefore, and all divisions, reissues, substitutions, continuations; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said application throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world, including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention, and all rights to register said invention in appropriate registries; and I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives.

I hereby further agree that I will communicate to said ASSIGNEE, or to its successors, assigns and legal representative, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all divisional, continuation, continuation-in-part, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

| in witness whereof, I he | ereto set my hand and seal at, |
|--|--|
| Miss | this 5th day of Septenber , 2000. |
| | $MM N \sim 1$ |
| $\overline{R_0}$ | bert S. Langer |
| 210 | and the same of th |
| Massales | AL. |
| STATE OF Massachusei | SS. |
| COUNTY OF Muddlesex | |
| Before me this 5th | day of September, 2000, personally appeared Robert S. |
| Langer known to me to be the pe | erson whose name of subscribed to the foregoing Assignment ted the same as his free act and deed for the purposes therein |
| | |
| • | Costove Deal |
| | NOTARY PUBLIC |
| [Notary's Seal Here] | My Commission Expires: 11/04/05 |
| | |
| | |
| | |
| IN WITNESS WHEREOF, I he | ereto set my hand and seal at, this, 2000. |
| | |
| | |
| Da | vid A. Putnam |
| | |
| STATE OF | |
| | SS. |
| COUNTY OF | · |
| Refore me this | day of 2000 personally appeared David A |
| | day of, 2000, personally appeared David A . person whose name of subscribed to the foregoing Assignment ted the same as his free act and deed for the purposes therein |
| | |
| | NOTARY PUBLIC |
| | HOTAKI I OBLIC |
| [Notary's Seal Here] Exchange.3116831.1 | My Commission Expires: |



(Number)

(Country)

Att_rney Docket No. 0492611-0326 (8151)

Yes No

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

This declaration is original.

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS

the specification of which (I authorize Choate, Hall & Stewart to check one of the following, three choices, and fill in the blanks, if applicable): is attached hereto. X was filed on 04/20/2000 as Application Serial No. 09/553,552 and amended on (if applicable). was filed as PCT international application No. (if and was amended under PCT Article 19 on applicable). I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledged the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56. I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: Prior Foreign Application(s): **Priority Claimed** Yes No (Country) (Day/Month/Year/Filed) (Number)

(Day/Month/Year/Filed)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

| 60/130,362 | <u>4/21/99</u> | Pending | | | | | |
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| (Application Serial No.) | (filing date) | (status-patented, pending, abandoned) | | | | | |
| (Application Serial No.) | (filing date) | (status-patented, pending, abandoned) | | | | | |
| PCT Applications designa | PCT Applications designating the United States: | | | | | | |
| (PCT Appl. No.) | (U.S.S.N.) | (status-patented, pending, abandoned) | | | | | |

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Sam Pasternack, Reg. No. 29,576; Brenda Herschbach Jarrell, Reg. No. 39,223; Kevin M. Tormey, Reg. No. 41,351; Elizabeth E. Nugent, Reg. No. 43,839; Karoline K.M. Shair, Reg. No. 44,332; Valarie B. Rosen, Reg. No. 45,689; Stanley C. Mah, Reg. No. 46,189.

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| Full name of first inventor: Robert S. Langer | |
|---|---------------|
| Inventor's signature: | |
| Residence: 77 Lombard Street, Newton, MA 021 | .58 |
| Citizenship: USA | |
| Post Office Address: Same | |
| Full name of second inventor: David A Putnam | <u> </u> |
| Inventor's signature: | Date: 9/14/00 |
| Residence: 143 Otis Street, Cambridge, MA 021 | 41 |
| Citizenship: USA | |
| Post Office Address: Same | |

Exchange.3116827.1



9:38AM

SEP.14,2000

ASSIGNMENT

Attorney Docket No. 0492611-0326 (8151)

WHEREAS, We, Robert S. Langer of Newton, Massachusetts and David A. Putnam of Cambridge, having invented certain new and useful improvements in ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS for which we will make application for United States Letters Patent; and

WHEREAS, MASSACHUSETTS INSTITUTE OF TECHNOLOGY a non-profit educational institute having offices at 77 Massachusetts Avenue, Cambridge, Massachusetts, and its successors and assigns (collectively hereinafter called "the Assignee"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledge, I do hereby sell assign and transfer unto said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive right, title and interest in and to said invention and in and to said application and all patents which may granted therefore, and all divisions, reissues, substitutions, continuations; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said application throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world, including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention, and all rights to register said invention in appropriate registries; and I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives.

I hereby further agree that I will communicate to said ASSIGNEE, or to its successors, assigns and legal representative, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all divisional, continuation, continuation-in-part, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

| in witness whereof, I he | ereto set m | y hand and seal at | ر |
|--|----------------------------|--|--|
| | this | day of | , 2000. |
| Ro | bert S. La | nger | |
| STATE OF | | | |
| COUNTY OF | | SS. ' | |
| Before me this | day oferson whosed the sam | , 2000, per e name of subscribed to t e as his free act and deed | sonally appeared Robert S. the foregoing Assignment for the purposes therein |
| | , | NOTARY PUBLIC | |
| [Notary's Seal Here] | | My Commission Expire | es: |
| IN WITNESS WHEREOF, I he | this 15 | day of Septende | 2:00 A- , 2000. |
| STATE OF Massrehus COUNTY OF Middlesey | ette | ' ss. | |
| Before me this | erson who ed the sam | se name of subscribed to e as his free act and deed | for the purposes therein |
| | | NOTARY PUBLIC | Joan Curties 12/14/2001 |
| [Notary's Seal Here] | | My Commission Expire | 12/14/2001 |